



Express Mail No.: ED 675 485 193 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

By: Lingyu Zhu *et al.*

Confirmation No.: 5561

Serial No.: 10/629,892

Art Unit: 1653

Filed: July 29, 2003

Examiner: Robert B. Mondesi

For: METHODS OF USING NON-HUMAN
ANIMAL APOLIPOPROTEIN A-I PROTEIN

Attorney Docket No.: 10173-084-999
(CAM:) (371855-999079)

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:

1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.

1b. A legible copy of :

☒ Each U.S. patent application publication and US and foreign patent. Pursuant to 37 CFR 1.98(a)(2) as amended (Federal Register, vol. 69, No.182, September 21, 2004, p.56510), a copy of U.S. patent is not submitted herewith;

☒ Each publication or that portion which caused it to be listed on the PTO-1449;

☐ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;

☒ all other information or portion which caused it to be listed on the PTO-1449.

1c. ☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.

1d. ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.

2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):

☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);

☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;

- ☐ Before the mailing of the first Office action on the merits;
- ☒ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

(Check either Item 3a or 3b)

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
☐ enclosed
☐ to be charged to Jones Day Deposit Account No. 50-3013.
- (Item 3b to be checked if any reference known for more than 3 months)*
4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The Certification Statement in Item 5 below is applicable.

The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:

- ☐ enclosed.
- ☐ to be charged to Jones Day Deposit Account No. 50-3013
5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked)

(Check either Item 5a or 5b)

- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- 5b. ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.
- 5c. ☐ Pursuant to 37 C.F.R. §1.704(d), each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.
6. ☐ This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).

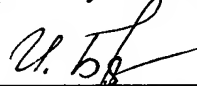
(Check appropriate Items 6a, 6b and/or 6c)

- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.
- 6b. ☐ Copies of publications listed on Form PTO-1449 from prior application Serial No. , filed on , of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. , filed on , and are provided herewith.
7. ☐ This is a Supplemental Information Disclosure Statement.
- 7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on . A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on .
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:
- (Check Item 8a, 8b, or 8c)
- 8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ set forth in the application.
- 8c. ☐ enclosed as an attachment hereto.
9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Jones Day Deposit Account No. 50-3013.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date: February 25, 2005

for


Irina E. Britva, Ph.D.
Anthony M. Insogna

JONES DAY
222 East 41st Street
New York, New York 10017
(212) 326-3939

50,498
(Reg. No.)
35,203

LIST OF REFERENCES CITED BY APPLICANT
(Use several sheets if necessary)

ATTY DOCKET NO.

101073-084-999

APPLICATION NO

10/629,892

APPLICANT

Lingyu Zhu et al.

FILING DATE

7/29/03

GROUP

1653

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
A01	6,037,323	03/14/00	Dasseux <i>et al.</i>	514	12	

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
					YES NO

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

C01	Altschul <i>et al.</i> , "Basic Local Alignment Search Tool," 1990, <i>J Mol Biol</i> 215(3):403-410
C02	Altschul <i>et al.</i> , "Gapped BLAST and PSI-BLAST: A New Generation of Protein Database Search programs," 1997, <i>Nucleic Acids Res</i> 25:3389-3402
C03	Babin, P.J., <i>et al.</i> , "Both Apolipoprotein E and A-I Genes are Present in a Nonmammalian Vertebrate and are Highly Expressed During Embryonic Development," (1997), <i>Proc. Natl. Acad. Sci. U.S.A.</i> , 94(16), pp. 8622-8627.
C04	Banerjee, D., <i>et al.</i> , "Biosynthesis of High Density Lipoprotein by Chicken Liver: Intracellular Transport and Proteolytic Processing of Nascent Apolipoprotein A-1," <i>J Cell Biol.</i> , (1985), 101(4), pp. 1219-1226.
C05	Beaubatie <i>et al.</i> , "Isolation and Characterization of the Major Plasma Apolipoproteins, A-I and B, in the European Badger, <i>Meles meles</i> ," 1986, <i>J Lipid Res</i> 27:140-149
C06	Bhattacharyya, N., <i>et al.</i> , "Isolation, Characterization and Sequencing of the Chicken Apolipoprotein AI Encoding Gene," (1991), <i>Gene</i> , 104(2), pp. 163-168.
C07	Blaton <i>et al.</i> , "Characterization of Babbon Plasma High-Density Lipoproteins and of Their Major Apoproteins," 1977, <i>Biochemistry</i> 16:2157-2163
C08	Brouillette <i>et al.</i> , "Structural Models of Human Apolipoprotein A-I: A Critical Analysis and Review," 2001, <i>Biochim Biophys Acta</i> 1531:4-46
C09	Byrnes, L., <i>et al.</i> , "Chicken Apolipoprotein A-I: cDNA Sequence, Tissue Expression and Evolution," (1987), <i>Biochem. Biophys. res. Commun.</i> , 148(1), pp. 485-492.
C10	Chen and Albers, "Interspecies Activation of Lecithin-Cholesterol Acyltransferase by Apolipoprotein A-I Isolated from the Plasma of Humans, Horses, Sheep, Goats and Rabbits," (1983), <i>Biochim. Biophys. Acta</i> , 753(1), pp. 40-46.
C11	Collet, X., <i>et al.</i> , "Evolution of Mammalian Apolipoprotein A-I and Conservation of Antigenicity: Correlation with Primary and Secondary Structure," (1997), <i>J Lipid Res.</i> , 38(4), pp. 634-644.
C12	Concha, M.I., <i>et al.</i> , "Local Expression of Apolipoprotein A-I Gene and a Possible Role for HDL in Primary Defence in the Carp Skin," (2003), <i>Fish Shellfish Immunol.</i> , 14(3), pp. 259-273.
C13	Ferrari, S., <i>et al.</i> , "The Complete Sequence of Chick Apolipoprotein AI mRNA and Its Expression in the Developing Chick," (1987), <i>Gene</i> , 60(1), pp. 39-46.
C14	Frank, P.G., <i>et al.</i> , "Apolipoprotein A-I: Structure-Function Relationships," (2000), <i>J Lipid Res.</i> , 41(6), pp. 853-872.
C15	GenBank Accession No. NM_000039
C16	GenBank Accession No. A56858
C17	GenBank Accession No. JT0672
C18	GenBank Accession No. A61448
C19	GenBank Accession No. CAA30377
C20	GenBank Accession No. X07496.1
C21	GenBank Accession No. S31394
C22	GenBank Accession No. LPCHA1
C23	Goulinet, S., <i>et al.</i> , "Plasma Lipoproteins in the Golden Syrian Hamster (<i>Mesocricetus Auratus</i>): Heterogeneity of

		apoB- and apoAI-Containing Particles," (1993), <i>J Lipid Res.</i> , 34(6), pp. 943-959.
	C24	Gu, Z.W., <i>et al.</i> , "Primary Structure of Beijing Duck Apolipoprotein A-1," (1993), <i>J Protein Chem.</i> , 12(5), pp. 585-591.
	C25	Jackson, R.L., <i>et al.</i> , "Isolation and Characterization of the Major Apolipoprotein From Chicken High Density Lipoproteins," (1976), <i>Biochim. Biophys. Acta.</i> , 420(2), pp. 342-349.
	C26	Januzzi, J.L., <i>et al.</i> , "Characterization of the Mouse Apolipoprotein ApoA-1/Apoc-3 Gene Locus: Genomic, mRNA, and Protein Sequences with Comparisons to Other Species," <i>Genomics</i> , 14(4), pp. 1081-1088.
	C27	Kelley, J.L., <i>et al.</i> , "Lipid Transport in the Avian Species. Part I. Isolation and Characterization of Apolipoproteins and Major Lipoprotein Density Classes of Male Turkey Serum," (1976), <i>Atheroscler.</i> , 24(1-2), pp. 155-175.
	C28	Kelley, J.L., <i>et al.</i> , "Lipid Transport in the Avian Species. Part 2. Isolation and Characterization of Lipoprotein A and Lipoprotein B, two major Lipoprotein Families of the Male Turkey Serum Lipoprotein System," (1976), <i>Atheroscler.</i> , 24(1-2), pp. 177-187.
	C29	Kiss, R.S., <i>et al.</i> , "Amphipathic Alpha-Helix Bundle Organization of the Lipid-Free chicken Apolipoprotein A-I," (1999), <i>Biochem.</i> , 38(14), pp. 4327-4334.
	C30	Lamon-Fava, S., <i>et al.</i> , "Evolutionary Distinct Mechanisms Regulate Apolipoprotein A-I Gene expression: Differences Between Avian and Mammalian apoA-I Gene Transcription Control Regions," (1992), <i>J Lipid Res.</i> , 33(6), pp. 831-842.
	C31	Li, W.H., <i>et al.</i> , "The Apolipoprotein Multigene Family: Biosynthesis, Structure, Structure-Function Relationships, and Evolution," (1988), <i>J Lipid Res.</i> , 29(3), pp. 245-271.
	C32	Liu, A.C., <i>et al.</i> , "Human Apolipoprotein A-I Prevents Atherosclerosis Associated with Apolipoprotein[a] in Transgenic Mice," (1994), <i>J Lipid Res.</i> , 35, pp. 2263-2267.
	C33	Luo, C.C., <i>et al.</i> , "Structure and Expression of Dog Apolipoprotein A-I, E, and C-I mRNAs: Implications for the Evolution and Functional Constraints of Apolipoprotein Structure," (1989), <i>J Lipid Res.</i> , 30, pp. 1735-1746.
	C34	Mezdour, H., <i>et al.</i> , "Exogenous Supply of artificial Lipoproteins does Not Decrease Susceptibility to Atherosclerosis in Cholesterol-fed Rabbits," (1995), <i>Atheroscler.</i> , 113, pp. 237-246.
	C35	Rajavashisth, T.B., <i>et al.</i> , "Structure, Evolution, and Regulation of Chicken Apolipoprotein A-I," (1987), <i>J Biol. Chem.</i> , 262(15), pp. 7058-7065.
	C36	Rubin, E.M., <i>et al.</i> , "Inhibition of Early Atherogenesis in Transgenic Mice by Human Apolipoprotein AI," (1991), <i>Nature</i> , 353, pp. 265-267.
	C37	Segrest, J.P., <i>et al.</i> , "Structure and Function of Apolipoprotein A-I and High-Density Lipoprotein," (2000), <i>Curr. Opin. Lipidol.</i> , 11(2), pp. 105-115.
	C38	Shackelford, J.E., <i>et al.</i> , "Synthesis and Secretion of Apolipoprotein A ₁ by Chick Breast Muscle," (1983), <i>J Biol. Chem.</i> , 258(11), pp. 7175-7180.
	C39	Smith <i>et al.</i> , "The Plasma Lipoproteins: Structure and Metabolism," 1978, <i>Ann Rev Biochem</i> 47:751-777
	C40	Sparrow <i>et al.</i> , "Plasma Lipid Transport in the Preruminant Calf, Bos spp: Primary Structure of Bovine Apolipoprotein A-I," 1992, <i>Biochim Biophys Acta</i> 1123:145-150
	C41	Sparrow, D.A., <i>et al.</i> , "Plasma Lipid Transport in the Hedgehog: Partial Characterization of Structure and Function of Apolipoprotein A-I," (1995), <i>J Lipid Res.</i> , 36(3), pp. 485-495.
	C42	Swaney, "1980, <i>Biochim Biophys Acta</i> 617:489-502
	C43	Trieu <i>et al.</i> , "Sequences and Expression of the Porcine Apolipoprotein A-I and C-III mRNAs," 1993, <i>Gene</i> 123(2):173-179
	C44	Trieu <i>et al.</i> , "Sequebce of the Porcine ApoA-I Gene," 1993, <i>Gene</i> 134 (2):267-270
	C45	Weiler-Guttler, H., <i>et al.</i> , "Synthesis of Apolipoprotein A-I in Pig Brain Microvascular Endothelial Cells," (1990), <i>J Neurochem.</i> , 54(2), pp. 444-450.
	C46	Yang, C.Y., <i>et al.</i> , "The Primary Structure of Apolipoprotein A-I from Rabbit High-Density Lipoprotein," (1986), <i>Eur. J Biochem.</i> , 160(2), pp. 427-431.
	C47	Yang, <i>et al.</i> , "The Complete Amino Acid sequence of Proapolipoprotein A-I of Chicken High Density Lipoproteins," (1987), <i>FEBS Lett.</i> , 224(2), pp. 261-266.
	C48	Yu, F.G., <i>et al.</i> , "Characterization of Lipoprotein Secreted by Cultured Eel Hepatocytes and Its Comparison with Serum Lipoproteins," (1991), <i>Cell Struct Funct.</i> , 16(4), pp. 347-355.

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.